K012173

SEP 2 8 2001

510(k) Summary

Submitter:	Sulzer Spine-Tech 7375 Bush Lake Road Minneapolis, Minnesota 55439
Date Prepared:	September 20, 2001
Contact:	Kristyn M. Benson Regulatory Affairs Associate
Proprietary Name:	Silhouette™ Spinal Fixation System
Common Name:	Rod, hook, and screw spinal instrumentation
Device Product Code & Classification:	Class II; MNI, MNH, and KWP
Predicate Device:	Silhouette™ Spinal Fixation System (K980288 & K992276)

Device Description:

The Silhouette™ Spinal Fixation System is a temporary implant system used to correct spinal deformity and to facilitate the biological process of spinal fusion. This system is intended for posterior use in the thoracic, lumbar, and sacral areas of the spine. Implants in this system consist of hooks and/or screws connected to rods that are intended to be removed after solid fusion has occurred. The system includes polyaxial screws of varying diameters and lengths, fixed screws of varying diameters and lengths, rods in varying lengths, hooks in varying designs, and transverse connectors in fixed and adjustable widths. All implant components are top loading and top tightening. The implants in this system are manufactured from titanium alloy (Ti-6Al-4V) that conforms to ASTM F-136.

Intended Use:

When used as a pedicle screw fixation system in skeletally mature patients, the Silhouette™ Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the Silhouette Spinal Fixation System is indicated for use in patients:

a) having severe spondylolisthesis (Grade 3 and 4) at the L5-S1 joint

b) who are receiving fusions with autogenous graft only
c) who are having the device fixed or attached to the lumbar or sacral spine
d) who are having the device removed after the development of a solid fusion mass

When used as a hook and sacral screw system, the Silhouette Spinal Fixation System is intended for use in the treatment of degenerative disc disease (as defined by chronic back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), idiopathic scoliosis, spondylolisthesis, kyphotic or lordotic deformity of the spine, loss of stability due to tumors, spinal stenosis, vertebral fracture or dislocation, pseudoarthrosis, and previous failed spinal fusion. When used for this indication, screws of the Silhouette Spinal Fixation System are intended for sacral iliac attachment only. Hook and transverse connectors of the system are intended for posterior thoracic and/or lumbar use only. As a whole, the levels of use for hook and sacral screw fixation of this system are T1 to the sacrum.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2001

Ms. Kristyn M. Benson
Regulatory Affairs Associate
Sulzer Spine-Tech
7375 Bush Lake Rod
Minneapolis, Minnesota 55439

Re: K012173
Trade Name: SILHOUETTE™ Spinal Fixation System 4.5mm pedicle screw
Regulation Number: 21 CFR 888.3050, 21 CFR 888.3070
Regulation Name: Appliance fixation, Spinal Interlaminal Fixation Orthosis;
Orthosis, Spondylolisthesis Spinal Fixation Device System,
Orthosis, Spinal Pedicle Screw Fixation Spinal System
Regulatory Class: Class II
Product Code: KWP, MNH, MNI
Dated: September 20, 2001
Received: September 21, 2001

Dear Ms. Benson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012173

INDICATIONS FOR USE STATEMENT

510(k) Number: K012173

Device Name: Silhouette™ Spinal Fixation System

Indications for Use:

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PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012173

Prescription Use X **OR** **Over-the-Counter-Use** _____
(Per 21 CFR 801.109)